#### **REMARKS**

#### Status of Claims

Upon entry of the present amendments, claims 1-4, 8-51, and 55-58 will be pending in this application. Previously pending claims 5, 7, and 52-54 are canceled. Claims 1-4, 8-51, and 55-58 are finally rejected.

Claim 1 is amended to include the subject matter of canceled claims 5 and 7, to delete reference to a self-emulsifying drug delivery system, and to specifically recite additional novel and beneficial features of the composition. Support for this amendment can be found on page 3, lines 4-8 and page 15, lines 4-8.

Claim 2 is amended to be dependent upon claim 1. Support for this amendment can be found on page 15, lines 4-8 and 12-13.

Claims 8-10, 17-19, 23-25, 27-30, 36-38, 40-42, 47-48, and 51 are amended to correct claim language informalities and to better present the invention.

No new matter has been added by way of these amendments.

## Claim Rejections

The rejections under 35 U.S.C. §§ 102, 103, and 112 are addressed in detail in Applicant's Amendment dated November 18, 2005. The rejections are further addressed briefly below.

# Rejection under 35 U.S.C. §112 - New Matter

The amended claims no longer make reference to a self emulsifying system. Accordingly, Applicants respectfully request that this rejection be withdrawn.

# Rejections under 35 U.S.C. §102

#### Grebow:

Grebow et al. (US 5,618,845) fails to explicitly or inherently disclose a surfactant.

Applicants note in this regard that Grebow's bare disclosure of an "emulsion" (col. 10, lines 20-21) is not an inherent disclosure of a surfactant. Merriam-Webster's Medical Dictionary (© 2002, Merriam-Webster, Inc.) defines an emulsion as "a system (as fat in milk) consisting of a liquid dispersed with or without an emulsifier in an immiscible liquid usually in droplets of larger than colloidal size" (emphasis added). The fact that an emulsion may contain an emulsifier is not sufficient to establish the inherency of a surfactant the Grebow emulsion (See MPEP § 2112 IV.)

Applicants respectfully request that this rejection be withdrawn.

#### Nguyen:

Nguyen et al. (US 5,843,347) fails to explicitly or inherently disclose *spontaneous* formation of an aqueous, homogeneous, stable composition. The composition of Nguyen must be stirred at high rpm to prepare achieve homogeneity (*see* col. 11, lines 25-30, col. 12, lines 47-49). Accordingly, the Nguyen composition is not a self-emulsifying drug delivery system.

Applicants respectfully request that this rejection be withdrawn.

#### Rejections under 35 U.S.C. §103

#### Grebow:

As previously discussed, Grebow fails to teach or suggest a surfactant. Applicants respectfully request that this rejection be withdrawn.

### Nguyen in view of Lafon:

As previously discussed, Nguyen fails to teach or suggest spontaneous formation of an

aqueous, homogeneous, stable composition.

Lafon fails to cure the deficiencies of Nguyen, since Lafon is not relied upon for a teaching of the form of the modafinil formulation.

Applicants respectfully request that this rejection be withdrawn.

#### Grebow in view of Lafon:

As previously discussed, Grebow fails to teach or suggest a surfactant.

Lafon fails to cure the deficiencies of Grebow, since Lafon is not relied on for a teaching of the form of the modafinil formulation.

Applicants respectfully request that this rejection be withdrawn.

# **Double Patenting Rejection**

Without agreeing to the substantive basis of the Examiner's rejection, and in order to expedite the prosecution, applicants submit herewith a Terminal Disclaimer in compliance with 37 CFR § 1.321(c).

Applicants respectfully request that this rejection be withdrawn.

#### Conclusion

Applicants:respectfully submit that each rejection has been addressed. It is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested. Applicants invite the Examiner to contact the undersigned at (610) 883-5679 to clarify any remaining issues.

Respectfully submitted,

Date: January 4, 2006

Todd W. Spradau Reg. No. 52,242

CEPHALON, Inc. 41 Moores Road P.O. Box 4011 Frazer, PA 19355

Telephone: 610-883-5679 Telefax: 610-738-6590